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NOTICE OF ALLOWANCE AND FEE(S) DUE

7590

07/30/2010

DENTSPLY INTERNATIONAL, INC.
570 West College Avenue
York, PA 18405-0872

EXAMINER

BRADLEY, CHRISTINA

ART UNIT

PAPER NUMBER

1654

DATE MAILED: 07/30/2010

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/628,692	07/28/2003	Brent L. Atkinson	CRM-P157/P	5172

TITLE OF INVENTION: BONE REPAIR PUTTY

APPLN. TYPE	SMALL ENTITY	ISSUE FEE DUE	PUBLICATION FEE DUE	PREV. PAID ISSUE FEE	TOTAL FEE(S) DUE	DATE DUE
nonprovisional	NO	\$1510	\$300	\$0	\$1810	11/01/2010

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. **PROSECUTION ON THE MERITS IS CLOSED.** THIS NOTICE OF ALLOWANCE IS NOT A GRANT OF PATENT RIGHTS. THIS APPLICATION IS SUBJECT TO WITHDRAWAL FROM ISSUE AT THE INITIATIVE OF THE OFFICE OR UPON PETITION BY THE APPLICANT. SEE 37 CFR 1.313 AND MPEP 1308.

THE ISSUE FEE AND PUBLICATION FEE (IF REQUIRED) MUST BE PAID WITHIN **THREE MONTHS** FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. **THIS STATUTORY PERIOD CANNOT BE EXTENDED.** SEE 35 U.S.C. 151. THE ISSUE FEE DUE INDICATED ABOVE DOES NOT REFLECT A CREDIT FOR ANY PREVIOUSLY PAID ISSUE FEE IN THIS APPLICATION. IF AN ISSUE FEE HAS PREVIOUSLY BEEN PAID IN THIS APPLICATION (AS SHOWN ABOVE), THE RETURN OF PART B OF THIS FORM WILL BE CONSIDERED A REQUEST TO REAPPLY THE PREVIOUSLY PAID ISSUE FEE TOWARD THE ISSUE FEE NOW DUE.

HOW TO REPLY TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

A. If the status is the same, pay the TOTAL FEE(S) DUE shown above.

B. If the status above is to be removed, check box 5b on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and twice the amount of the ISSUE FEE shown above, or

If the SMALL ENTITY is shown as NO:

A. Pay TOTAL FEE(S) DUE shown above, or

B. If applicant claimed SMALL ENTITY status before, or is now claiming SMALL ENTITY status, check box 5a on Part B - Fee(s) Transmittal and pay the PUBLICATION FEE (if required) and 1/2 the ISSUE FEE shown above.

II. PART B - FEE(S) TRANSMITTAL, or its equivalent, must be completed and returned to the United States Patent and Trademark Office (USPTO) with your ISSUE FEE and PUBLICATION FEE (if required). If you are charging the fee(s) to your deposit account, section "4b" of Part B - Fee(s) Transmittal should be completed and an extra copy of the form should be submitted. If an equivalent of Part B is filed, a request to reapply a previously paid issue fee must be clearly made, and delays in processing may occur due to the difficulty in recognizing the paper as an equivalent of Part B.

III. All communications regarding this application must give the application number. Please direct all communications prior to issuance to Mail Stop ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PART B - FEE(S) TRANSMITTAL

Complete and send this form, together with applicable fee(s), to: **Mail** **Mail Stop ISSUE FEE**
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INSTRUCTIONS: This form should be used for transmitting the ISSUE FEE and PUBLICATION FEE (if required). Blocks 1 through 5 should be completed where appropriate. All further correspondence including the Patent, advance orders and notification of maintenance fees will be mailed to the current correspondence address as indicated unless corrected below or directed otherwise in Block 1, by (a) specifying a new correspondence address; and/or (b) indicating a separate "FEE ADDRESS" for maintenance fee notifications.

CURRENT CORRESPONDENCE ADDRESS (Note: Use Block 1 for any change of address)

Note: A certificate of mailing can only be used for domestic mailings of the Fee(s) Transmittal. This certificate cannot be used for any other accompanying papers. Each additional paper, such as an assignment or formal drawing, must have its own certificate of mailing or transmission.

7590 07/30/2010
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 570 West College Avenue
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Certificate of Mailing or Transmission

I hereby certify that this Fee(s) Transmittal is being deposited with the United States Postal Service with sufficient postage for first class mail in an envelope addressed to the Mail Stop ISSUE FEE address above, or being facsimile transmitted to the USPTO (571) 273-2885, on the date indicated below.

(Depositor's name)
(Signature)
(Date)

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nonprovisional	NO	\$1510	\$300	\$0	\$1810	11/01/2010

EXAMINER	ART UNIT	CLASS-SUBCLASS
BRADLEY, CHRISTINA	1654	424-400000

1. Change of correspondence address or indication of "Fee Address" (37 CFR 1.363).

- ☐ Change of correspondence address (or Change of Correspondence Address form PTO/SB/122) attached.
☐ "Fee Address" indication (or "Fee Address" Indication form PTO/SB/47; Rev 03-02 or more recent) attached. Use of a **Customer Number is required.**

2. For printing on the patent front page, list

- (1) the names of up to 3 registered patent attorneys or agents OR, alternatively, 1 _____
 (2) the name of a single firm (having as a member a registered attorney or agent) and the names of up to 2 registered patent attorneys or agents. If no name is listed, no name will be printed. 2 _____
 3 _____

3. ASSIGNEE NAME AND RESIDENCE DATA TO BE PRINTED ON THE PATENT (print or type)

PLEASE NOTE: Unless an assignee is identified below, no assignee data will appear on the patent. If an assignee is identified below, the document has been filed for recordation as set forth in 37 CFR 3.11. Completion of this form is NOT a substitute for filing an assignment.

(A) NAME OF ASSIGNEE

(B) RESIDENCE: (CITY and STATE OR COUNTRY)

Please check the appropriate assignee category or categories (will not be printed on the patent): ☐ Individual ☐ Corporation or other private group entity ☐ Government

4a. The following fee(s) are submitted:

- ☐ Issue Fee
☐ Publication Fee (No small entity discount permitted)
☐ Advance Order - # of Copies _____

4b. Payment of Fee(s): (Please first reapply any previously paid issue fee shown above)

- ☐ A check is enclosed.
☐ Payment by credit card. Form PTO-2038 is attached.
☐ The Director is hereby authorized to charge the required fee(s), any deficiency, or credit any overpayment, to Deposit Account Number _____ (enclose an extra copy of this form).

5. Change in Entity Status (from status indicated above)

- ☐ a. Applicant claims SMALL ENTITY status. See 37 CFR 1.27. ☐ b. Applicant is no longer claiming SMALL ENTITY status. See 37 CFR 1.27(g)(2).

NOTE: The Issue Fee and Publication Fee (if required) will not be accepted from anyone other than the applicant; a registered attorney or agent; or the assignee or other party in interest as shown by the records of the United States Patent and Trademark Office.

Authorized Signature _____ Date _____
 Typed or printed name _____ Registration No. _____

This collection of information is required by 37 CFR 1.311. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, Virginia 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

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07/28/2003

Brent L. Atkinson

CRM-P15F/P

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BRADLEY, CHRISTINA

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Determination of Patent Term Adjustment under 35 U.S.C. 154 (b) (application filed on or after May 29, 2000)

The Patent Term Adjustment to date is 510 day(s). If the issue fee is paid on the date that is three months after the mailing date of this notice and the patent issues on the Tuesday before the date that is 28 weeks (six and a half months) after the mailing date of this notice, the Patent Term Adjustment will be 510 day(s).

If a Continued Prosecution Application (CPA) was filed in the above-identified application, the filing date that determines Patent Term Adjustment is the filing date of the most recent CPA.

Applicant will be able to obtain more detailed information by accessing the Patent Application Information Retrieval (PAIR) WEB site (<http://pair.uspto.gov>).

Any questions regarding the Patent Term Extension or Adjustment determination should be directed to the Office of Patent Legal Administration at (571)-272-7702. Questions relating to issue and publication fee payments should be directed to the Customer Service Center of the Office of Patent Publication at 1-(888)-786-0101 or (571)-272-4200.

Notice of Allowability**Application No.**

10/628,692

Applicant(s)

ATKINSON ET AL.

Examiner

CHRISTINA BRADLEY

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the response filed 05/14/2010.
2. ☒ The allowed claim(s) is/are 1-8,10,12-14 and 19.
3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
(b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08),
Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

/Christina Marchetti Bradley/
Examiner, Art Unit 1654

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Leana Levin on 07/08/2010.

The application has been amended as follows:

Claim 1. (Currently amended) A bone repair putty material, comprising:

a porous, resorbable particulate ~~selected from~~derived of an organic bone mineral, ~~or a~~ natural bone-derived material, ~~or and a~~ synthetic hydroxyapatite, said particulate in a concentration of 55 to 60 weight percent ~~or greater of said material~~, said particulate and having a bulk density of 1.1 to 1.3 g/cc; and

a resorbable carrier gel component for suspending said particulate, forming a putty[[-like]] formulation, for placing in a bony defect, said gel component having a sufficiently high molecular weight and concentration in the putty such that bone repair is facilitated while migration and expansion of said particulate is minimized.

Claim 2. (Original) The bone repair material of claim 1 wherein said resorbable particulate is bovine-derived having a particle size range of 250 to 1000 μm .

Claim 3. (Original) The bone repair material of claim 1 wherein said resorbable particulate is a porous hydroxyapatite derived from lime-containing algae, having a particle size range of 300-1000 μm .

Claim 4. (Original) The bone repair material of claim 1, wherein said carrier gel component comprises a polysaccharide.

Claim 5. (Previously presented) The bone repair material of claim 4, wherein said carrier gel component is hyaluronic acid or its derivatives, or hydroxylpropyl cellulose or mixtures thereof.

Claim 6. (Currently Amended) The bone repair material of claim 5, wherein said carrier gel component is hyaluronic acid or its derivatives having a molecular weight of $0.7\text{-}2.0 \times 10^6$ D[[d]]altons and a final concentration of 45-64 mg/cc in the putty.

Claim 7. (Previously presented) The bone repair material of claim 1, further comprising at least one P-15 synthetic biomimetic, polypeptide sequence of Type I collagen bound to said particulate.

Claim 8. (Currently amended) A bone repair putty material for dental bone repair procedures, comprising:

a porous, ~~synthetic~~, resorbable particulate selected from~~[[,]]~~ a synthetic, bone-like hydroxyapatite and an organic bone-derived particulate, ~~in an amount of 55 weight percent or greater of said material~~, said particulate in a concentration of 55 to 60 weight percent and having a bulk density of 1.1 to 1.3 g/cc; and

a hyaluronic acid gel ~~in an amount of about 25-70 weight percent of said material~~, wherein said material is a moldable, cohesive putty for application to bony defects.

Claim 9. (Canceled)

Claim 10. (Currently amended) The bone repair material of claim 8, wherein said bone repair material comprises ~~about~~ 55 weight percent particulate and ~~about~~ 45 weight percent hyaluronic acid gel.

Claim 11. (Canceled)

Claim 12. (Currently Amended) The bone repair material of claim 4, wherein said carrier gel is a hydroxylpropyl cellulose or methyl cellulose gel forming a moldable, cohesive putty.

Claim 13. (Currently Amended) The bone repair material of claim 8 further comprising ~~at least one of~~ a P-15 polypeptide sequence of collagen bound to the porous, restorable particulate, wherein said particulate is a xenogen~~[[c]]~~ic bone mineral particulate of about 200-500 mm in diameter, ~~suspended in said gel carrier, said material having a putty-like consistency.~~

Claim 14. (Currently Amended) The bone repair material of claim 3 further comprising ~~at least one of a~~ P-15 polypeptide sequence of collagen bound to said porous hydroxyapatite derived from lime containing algae of about 300-1000 μm in diameter, and wherein said carrier is suspended in hydroxypropyl cellulose or hyaluronic gel carrier, said material having a putty-like consistency.

Claims 15-18 (Canceled).

Claim 19. (Currently Amended) The bone repair material of claim 7, wherein the concentration of P-15 synthetic biomimetic, polypeptide sequence of Type I collagen in the putty is at least ~~about~~ 800 mg/cc.

Insert the following sentence before the first sentence of the specification:

--This application claims priority under 35 U.S.C. 119(e) to provisional Application No. 60/399,851, filed 07/31/2002.--

2. Support for the amendments to the claims is found, for example, in original claim 9 which recites a particulate concentration of about 50 to 60 weight percent, said particulate having a bulk density of 1.1 to 1.3 g/cc, Example 11 which includes a material comprising 55 weight percent particulate, said particulate having a bulk density of 1.2 g/cc, and original claim 10 which recites about 55 weight percent particulate percent, said particulate having a bulk density

of 1.1 to 1.3 g/cc. The carrier in original claims 9 and 10 is limited to hyaluronic acid and the carrier in Example 11 is hydroxypropyl cellulose (HPC) and may also be hyaluronic acid.

3. Support for the amendment to the specification is found in the Oath filed 11/10/2003, which is four months from the actual filing date of the application, 07/28/2003. Because the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., the reference was submitted in an oath or declaration), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required.

4. The following is an examiner's statement of reasons for allowance: The closest prior art of Gertzman et al. (US 6,030,635) teach bone repair putty materials comprising a particulate component selected from 30 and 33% cortical allograft bone, and a carrier component selected from 2 or 3% hyaluronic acid, 20 % dextran 40 PM, 20% pluronic acid F127 and 20% pluronic acid F108 (Table 1, examples I and IV-VIII), each of which are putty with "excellent formability". In addition, Gertzman et al. teach a bone repair putty material comprising a particulate component of 50% cortical allograft bone powder and a carrier component selected from 20% pluronic F127, 20% pluronic F108 and 3% chitosan (Table 1, examples II, III, XII or XIII), each of which are putty with "poor formability" and are "too grainy, too dry" (Table 1). The reference does not teach a bone repair putty material comprising 55 to 60 weight percent particulate. In addition, the reference does not teach that the particulate has a bulk density of 1.1 to 1.3 g/cc or discuss the effect of bulk density on the properties of the putty material. Although

Gertzman et al. teach that it is desirable to maximize “the amount of bone in the formulation without creating a gritty, less malleable characteristic” (col. 4, Ins. 30-35), all of the compositions taught by Gertzman et al. that approach the concentrations of particulate recited in the instant claims all have “poor formability” and are “too grainy, too dry” (Table 1). The reference does not suggest increasing the amount of bone particulate to 55 to 60 weight percent or avoiding the properties of the putty by selecting a particulate with a bulk density of 1.1 to 1.3 g/cc. Thus, the claimed bone repair material is both novel and unobvious over Gertzman et al.

5. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled “Comments on Statement of Reasons for Allowance.”

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRISTINA BRADLEY whose telephone number is (571)272-9044. The examiner can normally be reached on Monday, Tuesday, Thursday and Friday 8:30 A.M. to 4:30 P.M.

7. If attempts to reach the examiner by telephone are unsuccessful, the examiner’s supervisor, Cecilia Tsang can be reached on (571) 272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

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system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Christina Marchetti Bradley/
Examiner, Art Unit 1654

cmb